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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/667,821      | 09/22/2003  | Andrew Thurkauf      | 97,033-U1           | 1016             |

7590

12/27/2004

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| EXAMINER |
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BERNHARDT, EMILY B

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| ART UNIT | PAPER NUMBER |
|----------|--------------|

1624

DATE MAILED: 12/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/667,821

Applicant(s)

THURKAUF ET AL.

Examiner

Emily Bernhardt

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3,5-12 and 36-67 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-12 and 36-67 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

In view of applicants' response filed 10/4/04 the following still applies.

Claims 1-3,5-12,36-67 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. Reason #3 of the previous action remains. While applicants have amended the main claims to recite assay conditions the testing conditions are incomplete since the nature of the cell line is incomplete as well as type of radioligand employed. There are different types of COS cell lines including COS-1 and COS-7 that are routinely used for screening for various receptor activity. Both of these would affect measurement of  $K_i$  values and thus intended scope. See Table 3 in Blenau article provided with this action for variation in  $K_i$  values when employing various cell lines and/ or radioligands.

The 102 rejection is overcome by applicants' amendments to claim 3.

The rejection over Prasad is withdrawn in view of applicants' remark regarding the absence of activity data for prior art compound relied on and thus no motivation to further modify it.

The rejection over Morren is withdrawn since it is noted that the reference generically teaches higher chains and not benzyl and the species disclosed are even

further removed having all butylenes as a chain link between phenyl and piperazine ring vs. instant methylene.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1,2,7-10,36-45,50-53,56-57,62-65 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Mokrosz for reasons of record.

Applicants' traverse to this rejection is not persuasive for the following reasons. While no express teaching to substitute methyl for hydrogen or change the position of a ring substituent is disclosed in Mokrosz, where claimed compounds are so similar in structure to prior art compounds, sufficient motivation does exist to make the claimed compounds in the expectation that compounds of structural similarity will have similar properties.

Note the case law previously cited in which an equivalency teaching was not needed and still claims were refused. Also note Ex parte Henkel 130 USPQ 474 which also dealt with position isomerism and the addition of methyl in which no express teaching was needed. Thus absent evidence of superior, unexpected results with prior art compounds previously pointed out the rejections remain.

The double patenting rejections over the claims of various parents as set forth in the previous action is overcome by the Terminal Disclaimer filed on 10/4/04.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Bernhardt whose telephone number is 571-272-0664.

If attempts to reach the examiner by telephone are unsuccessful, the acting supervisor for AU 1624, James O. Wilson can be reached at 571-272-0661. The

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Art Unit: 1624

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fax phone number for the organization where this application or proceeding is  
assigned is (571) 273-8300.

*E. Bernhardt*

Emily Bernhardt  
Primary Examiner  
Art Unit 1624